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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/624,855	07/25/2000	Robert Tam	213/102-US4	6566

29858 7590 10/15/2004

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EXAMINER	
OWENS JR, HOWARD V	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 10/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/624,855	TAM, ROBERT	
	Examiner	Art Unit	
	Howard V Owens	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/1/2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2 and 17-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *2 and 17-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Arguments

The following is in response to the amendment filed 3/1/2004:

An action on the merits of claims 2 and 17-19 is contained herein below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's arguments filed 3/1/2004 have been fully considered but they are not persuasive.

Claims 2 and 17 - 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Brillanti et al., *Gastroenterology*, Vol. 107, 812-817, 1994.

Claim 2 is drawn to a method of modulating Type 1 and Type 2 responses of lymphocytes contained within an environment by administration of Ribavarin and interferon in a concentration which increases the Type 1 response and suppresses the Type 2 response.

Dependent claims 17 - 19 are drawn to a ribavirin concentration of .25 – 6.7 μM in a medium supporting the T cells with further administration of alpha interferon.

Brillanti teaches the treatment of Hepatitis C, a disease which affects the liver and hepatocytes, via administration of ribavirin and alpha interferon. Although Brillanti does not specifically disclose the increase of the Type 1 response and suppression of the Type 2 response, the Type 1 and Type 2 response is seen as merely an affect of the administration of ribavarin and thus an inherent property. In claim 2 the Type 1 and Type 2 responses (and modulation thereof) are effects of the practice of the method. The main body of the claim is the administration of ribavarin or ribavarin and interferon. The prior art may anticipate even if those of ordinary skill in the art did not recognize the inherent characteristic or functioning of the prior art. "Insufficient prior understanding of the inherency properties of a known composition does not defeat a finding of anticipation".*Atlas Powder, 190 F.3d 1349.*

Applicant argues that the invention is non inherently achieved. Other than the statement that *Atlas* is not the sole determinant for an inherency inquiry applicant does not offer any arguments which demonstrate why the teachings of Brillanti do not inherently disclose the invention as claimed. Applicant argues that the property/result claimed must be recognized by one of skill in the art, citing *Continental Can Co. v. Monsanto* Co., 948 F.2d 1264, 1268 (Fed.cir. 1991). However, the question of novelty/inherency has been more recently addressed in *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362 (1999), wherein it was recognized that the key recognition lies in whether the result would naturally flow from the method and inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art (emphasis added).

"Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient. Thus, a prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it". *MEHL/Biophile*, 1365.

"Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates. Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art". *MEHL/Biophile*, 1366.

Brillanti administers Ribavirin up to 800 mg/day, which equates to a serum concentration maximum of 6.7μM as recognized by applicant on p. 10 of the specification. Brillanti also teaches the limitation of combining ribavirin with interferon. Applicant claims the promotion and suppression of Th1/Th2 with the same dosage range set forth in Brillanti. There is no evidence set forth by applicant that there are two distinct patient populations within the dosage/concentration range. Those suffering from

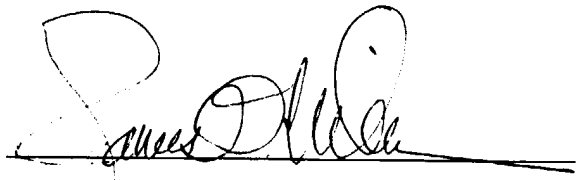
Hepatitis C are theoretically treated with the same dosage for non-hepatitis conditions, thus the recognition of Th1/Th2 modulation is an effect recognized by applicant. As such, the prior art of Brillanti necessarily functions in accordance with the claimed invention and limitations thereto.

For the reasons set forth above, the rejection of record is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Howard V. Owens
Patent Examiner
Art Unit 1623



James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (571) 272-0658 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (571) 272 - 0661.